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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,742	08/04/2003	Michael Spaid	100/15901	6619

21569 7590 08/16/2006

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,742	SPAID ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *8,19,26 and 33-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-18,20-25 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/1/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-8, 9-18, 20-25, 27-32 in the reply filed on July 11, 2006 is acknowledged.

2. Claims 8, 19, 26, 33-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 11, 2006.

3. Claims 1-8, 9-18, 20-25, 27-32 are currently under examination.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-8, 9-18, 20-25, 27-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. With respect to claims 1, 11, Loh et al. teach measuring the dispersion and relating the dispersion to the interaction between the plurality of molecules. However, it is unclear how the dispersion of a molecule and the interaction of molecules are related. More specifically, it is not clear if the molecules do not interact if dispersion would occur, and if so, how it would be differentiated from molecules that do interact. If dispersion does not necessarily occur, then there is also a lack of antecedent basis for "the dispersion", as it would not be a property inherent in the molecules.

7. With respect to claim 1, it is unclear if the limitation "wherein the dispersion of the molecules is Taylor-Aris dispersion" is intended to mean that applicants are only measuring Taylor-Aris dispersion" or that the molecules only undergo Taylor-Aris dispersion. Currently, it is believed that applicant's intend the latter meaning, as it is unclear how molecules could only be limited to Taylor-Aris dispersion; however, from the way the limitation is recited, it could reasonably be assumed that the former interpretation is intended. Clarification would be greatly appreciated.

8. Claim 2 recites the limitation "the molecules" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. It is unclear if "the molecules" is referring to "a plurality of molecules" or to "at least one of the molecules". It is noted that applicant has used "the molecules" in claim 1; however, this was believed to refer to "a plurality of molecules", as therefore were no other previous recitations of molecules. In claim two, however, the recitation of "the molecules" is ambiguous, as the phrase could refer to two different sets of molecules. This is also applicable to claims 4-5, 6, 10.

9. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-6, 9, 11, 13-18, 20, 21, 25, 27, 30, 32, are rejected under 35 U.S.C. 102(b) as being anticipated by Loh et al. [Loh et al., Taylor-Aris diffusion studies of solute-polymer interactions. 1. Alkyl p-hydroxybenzoates with an ABA block copolymer (poloxamer P407) in aqueous solution, 1994, Langmuir 10, 3431-3434].

With respect to claims 1, 11, Loh et al. teach Taylor-Aris diffusion studies of the interaction between Pluronic P407 and alkyl p-hydroxybenzoates (p.3433, col.1), wherein the solute was injected into a 7m long stainless steel tube with an internal radius 0f 0.360 mm (microfluidic conduit) and the dispersion recorded via a UV detector (column 3432, col.1).

12. With respect to claim 2, Loh et al teach that the solute is injected into the tube (p.3432, col.1). Therefore, the polymer and benzoates would be subjected to some pressure driven flow (during the injecting).

13. With respect to claim 3, Loh et al. teach the detection of the diffusion coefficient in the absence of polymer (p.3433, col.2).

14. With respect to claims 4, 17, Loh et al. teach that the polymer volume fractions were calculated using the specific volumes reported (concentrations) (p.3433, col.2).

15. With respect to claim 5, although Loh et al. do not specifically state that the molecules are not labeled, Loh et al do not teach the use of a label (p.3432, cols. 1-2).

16. With respect to claims 6, 25, Loh et al. teach paraben/P407 interaction via hydrogen bonding (p.3434, col.2), which is an associative interaction.

17. With respect to claims 9, 27, Loh et al. teach Taylor-Aris diffusion studies of the interaction between Pluronic P407 (polymers) and alkyl p-hydroxybenzoates (p.3433, col.1).

18. With respect to claim 16, Loh et al. teach Taylor-Aris diffusion studies of the interaction between Pluronic P407 and alkyl p-hydroxybenzoates (p.3433, col.1). Therefore the molecules would have to be in fluid communication in order to interact.

19. With respect to claims 13-15, 32, Loh et al teach that the solute (which contains both the polymer and the alkyl p-hydroxybenzoates) is injected into the tube (p.3432, col.1). The injection of solute could therefore be considered a bolus of fluid, and would not constitute side by side streams.

20. With respect to claim 18, Loh et al teach the use of a solvatochromic dye to probe aqueous solutions of the polymer and to use UV detection (p.3432, col.2).

21. With respect to claim 20, Loh et al. teach the detection of the diffusion coefficient of paraben (first molecule) in the absence of polymer (second molecule) (p.3433, col.2).

22. With respect to claim 21, Loh et al. teach the detection of the diffusion coefficient of paraben (second molecule) in the absence of polymer (first molecule) (p.3433, col.2).

23. With respect to claim 30, Loh et al. further teach measuring the diffusion coefficients of caffeine and β-phenylalanine (p.3432, col.1).

24. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Loh et al. [Loh et al., Taylor-Aris diffusion studies of solute-polymer interactions. 1. Alkyl p-hydroxybenzoates with an ABA block copolymer (poloxamer P407) in aqueous solution, 1994, Langmuir 10, 3431-3434] in light of Bello et al. [Bello et al., Use of Taylor-Aris dispersion for measurement of solute diffusion coefficient in thin capillaries, 1994, Science 266, p.773-776].

With respect to claim 31, Loh et al. teach Taylor-Aris diffusion studies of the interaction between Pluronic P407 and alkyl p-hydroxybenzoates (p.3433, col.1), wherein the solute was

injected into a 7m long stainless steel tube with an internal radius 0f 0.360 mm (microfluidic conduit) and the dispersion recorded via a UV detector (column 3432, col.1). Although Loh et al do not specifically teach measuring longitudinal dispersion in the axis of flow, one of ordinary skill in the art would know in order to measure Taylor-Aris dispersion, would involve measuring longitudinal dispersion in the axis of flow, as evidenced by Bello et al. (p.774, col.1, bottom).

Claim Rejections - 35 USC § 103

25. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

26. Claims 7, 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loh et al. [Loh et al., Taylor-Aris diffusion studies of solute-polymer interactions. 1. Alkyl p-hydroxybenzoates with an ABA block copolymer (poloxamer P407) in aqueous solution, 1994, Langmuir 10, 3431-3434] in view of Hefti [US 6,287,874].

With respect to claims 7, 28 29, Loh et al. teach Taylor-Aris diffusion studies of the interaction between a plurality of molecules (Pluronic P407 and alkyl p-hydroxybenzoates) (p.3433, col.1), wherein the solute was injected into a 7m long stainless steel tube with an internal radius 0f 0.360 mm (microfluidic conduit) and the dispersion recorded via a UV detector (column 3432, col.1). Loh et al. do not teach that the plurality of molecules comprises a receptor and ligand, or more specifically, an enzyme and substrate.

Hefti, however, teaches the measurement of enzyme/substrate interactions (column 6, lines 23-45) involving measurement of dispersion effects (column 26, lines 1-5). Hefti further provides motivation for doing so by teaching that proteins play a variety of key roles in biological processes, and that by screening large libraries of compounds for their ability to bind protein targets of interest, ligands identified as binding to the target can be used to develop more focused libraries, resulting in the identification of lead compounds that are subjected to various pharmaceutical analyses to select useful drug candidates (column 1, lines 45-67).

Therefore, it would have been obvious to one of ordinary skill in the art to study the interaction of receptors and ligands, more specifically enzymes and substrates, in the method of Loh et al, as suggested by Hefti, in order to identify lead compounds that can be subjected to various pharmaceutical analyses to select useful drug candidates.

27. Claims 10, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loh et al. [Loh et al., Taylor-Aris diffusion studies of solute-polymer interactions. 1. Alkyl p-hydroxybenzoates with an ABA block copolymer (poloxamer P407) in aqueous solution, 1994, Langmuir 10, 3431-3434].

With respect to claims 10, 22-24, Loh et al teach molecules with diffusion ratios (p.3433, col.2), but fail to specifically teach diffusivity ratios of at least about 2, about 8-10, or greater than 10. However, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

28. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Loh et al. [Loh et al., Taylor-Aris diffusion studies of solute-polymer interactions. 1. Alkyl p-hydroxybenzoates with an ABA block copolymer (poloxamer P407) in aqueous solution, 1994, Langmuir 10, 3431-3434] in view of Parce et al. [US 6,149,870].

With respect to claim 12, Loh et al. teach Taylor-Aris diffusion studies of the interaction between a plurality of molecules (Pluronic P407 and alkyl p-hydroxybenzoates) (p.3433, col.1), wherein the solute was injected into a 7m long stainless steel tube with an internal radius 0f 0.360 mm (microfluidic conduit) and the dispersion recorded via a UV detector (column 3432, col.1). Loh et al. further teach determining the diffusion coefficient of different concentrations of the polymer (0.5, 1.0, 2.0 % solutions) (p.3433, col.2). Loh et al. do not teach that the first molecule is introduced into the microfluidic conduit in a continuous stream of fluid.

Parce et al., however, teach that using a continuous flow arrangement to achieve a desired dilution (column 8, lines 20-43), and further teach that the arrangement allows for successive dilutions with the same sample (column 8, liens 61-67). This would be advantageous in the system of Loh et al., as it would allow for the determination of the diffusional coefficient of different concentrations of polymers to be determined in the same assay.

Therefore, one of ordinary skill in the art would have been motivated to have a continuous flow arrangement to achieve a desired concentration of polymer in the method of Loh et al., as suggested by Parce et al., in order to allow for the determination of the diffusional coefficient of different concentrations of polymers to be determined in the same assay.

Conclusion

29. No claims are allowed.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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